

**Food and Drug Administration, HHS****§ 888.3520**

declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

**§ 888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.**

(a) *Identification.* A knee joint femorotibial metal/composite non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon fibers composite and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

**§ 888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.**

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

**§ 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.**

(a) *Identification.* A knee joint femorotibial metal/polymer constrained cemented prosthesis is a de-

vice intended to be implanted to replace part of a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. The generic class also includes devices whose upper and lower components are linked with a solid bolt passing through a journal bearing of greater radius, permitting some rotation in the transverse plane, a minimal arc of abduction/adduction. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

**§ 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.**

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage